Protection of medicinal plants

1520. SHRI RAMA MUNI REDDY SIRIGIREDDY: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that medicinal plants in the country are rapidly on extinct;

(b) if so, the steps taken by his Ministry to protest the medicinal plants in the country;

(c) whether any action plan has been formulated for this purpose; and

(d) if so, the details thereof?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA): (a) There is no evidence that medicinal plants are becoming extinct rapidly in the country.

(b) to (d) However, Government have taken steps to encourage conservation and cultivation of plants species through various schemes such as *in-situ*/*ex-situ* conservation, Biosphere Reserves, establishment of Gene Banks and developing Agro-techniques. A Medicinal Plants Board has also been set up which will coordinate activities relating to conservation and cultivation of medicinal plants.

Permission for new drug

1521. SHRI KHAN GHUFRAN ZAHIDI: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the number of applications received during the year 2001, for new drug permission, Bio-equivalence permission;

(b) how much time it will take to grant the final permission on these applications;

(c) whether DCGI has discretionary powers in granting the new drug permission; and

(d) if so, how many permission have been granted under discretionary powers?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA): (a) The following are the number of new drug Applications received during the year 2001:
1. Investigational New Drug (IND)-2
2. New Drug Applications-56
3. Subsequent Applications for New Drug approval requiring Bio-equivalence studies-about 400.

(b) to (d) Application for permission for Clinical trials. Bio-equivalence studies and marketing of new drugs are examined by the New Drug Division in the office of DCG (I). The requirement for granting such approval are specified in Rules 122A, 122B, 122C, 122D, 122E and Schedule Y of Drugs and Cosmetics Rules. The evaluation of new drug clinical trial is a complex process and varies according to the nature of molecule drug published data and information furnished by applicants. Therefore, depending upon the nature of the application, it may take on an average more than 5 years for approval of investigation New Drug (i.e. a drug molecule not tested on human beings anywhere in the world), about 1-3 years for the first time approval of the drug already approved elsewhere but requiring confirmatory clinical trial, and about 2-3 months for subsequent applications for already approved drugs. This is, however, subject to submission of all required data as per provisions of Schedule Y of Drug and Cosmetics Rules. Certain critical drugs e.g. anti-cancer, anti-HIV etc., which are important from the point of view of public health are also cleared on a fast track basis. Permissions are granted after taking into account the technical requirements and not on discretion.

Increase in cancer patients

†1522. PROF. R.B.S. VARMA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that the number of cancer patients is increasing in the country;

(b) if so, the details thereof;

---

†Original notice of the question was received in Hindi.